

ATTENTION:

THIS MANUAL OF INSTRUCTIONS REFERS TO
STRIAT EQUIPMENT MANUFACTURED BY
IBRAMED



*PLEASE READ THIS MANUAL
CAREFULLY BEFORE USING THE
EQUIPMENT AND ALWAYS REFER
TO IT WHENEVER DIFFICULTIES
APPEAR. KEEP THIS MANUAL
ALWAYS AT HAND.*

Manual of Instruction STRIAT – 5th edition (Revision 06/2008)
This instruction manual was elaborated by Prof. Dr. Elaine C. Guirro

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ATTENTION
RISK OF ELECTRICAL SHOCK
DO NOT OPEN IT



The lightning bolt symbol inside a triangle is a warning about the presence of “dangerous voltage”, without insulation in the internal part of the equipment which may be strong enough to cause risk of electrical shock.



An exclamation mark inside a triangle alerts the user about the existence of important operation and maintenance instructions (technical service) for this equipment.

ATTENTION: To prevent electrical shock do not use the equipment plug attached to an extension cable or to any other type of plug except that the terminals fit perfectly in the receptacle. Disconnect the input plug from socket when not using the equipment for a long period of time.

General care with the equipment



STRIAT is an equipment that does not required special safety measures in its installation. We suggest that you:

- ◆ Avoid places exposed to vibration.
- ◆ Install the equipment on a firm and horizontal surface, in a site with perfect ventilation.
- ◆ Avoid humid, hot and dusty places. *This equipment is not protected against harmful water penetration.*
- ◆ Place the cable in order to leave it free, out of places where it can be trodden on, and do not place any furniture over it.
- ◆ Do not insert objects into equipment orifices and do not place recipients with liquid on it.
- ◆ Do not use volatile substances (benzene, alcohol, thinner and solvents in general) to wipe the equipment cabinet because they can damage the finishing. Use only a soft, dry, and clean piece of cloth.

Explicação dos símbolos utilizados



- **ATTENTION!** Check and follow the instructions in this manual.



- Equipment CLASS II. The protection against electric shock is not based only in the basic insulation but also incorporates additional safety precautions, such as double or reinforced insulation, not holding grounding resources protection or depending on installation conditions.



- Equipment with BF applied part.



Risk of electrical shock.



- Indicates electrostatic discharge sensibility

IPX0 - Equipment not protected against harmful water dripping.

V~ - Volts in Alternate Current

~ line - Alternate current power line

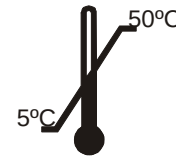
In the Transportation Box:



- **FRAGILE:** The content in this package is fragile and should be handled with care.



- **THIS SIDE UP:** Indicates the correct position to ship the package.



- **TEMPERATURE LIMITS:** Indicates the limit temperatures for transportation and storage the package.



- **KEEP IT AWAY FROM THE RAIN:** This package should not be shipped under rain.



- **MAXIMUM STACKING NUMBER:** The maximum number of identical packages which can be stacked. For this equipment, the limit stacking number is 10 units.

Preliminary observations

STRIAT is an equipment manufactured for use in dermato functional area (esthetics) and traumato-ortopedia. It does not cause dependence and has no undesirable side effects, and it could be used ionization in all esthetic treatments to combat wrinkles and stretch marks. The equipment corresponds to safety and protection **CLASS II** type **BF**. It must be operated only by qualified professionals and in properly authorized medical departments. *The use of these units is not intended for rooms with risk of explosion such as anesthesia departments or the presence of an anesthetic flammable mixture with air; oxygen or nitric oxide.*

POTENTIAL ELETROMAGNETIC INTERFERENCE: *As for the limits regarding electromagnetic disturbance, Striat is electro-medical equipment that belongs to Group 1, Class A. The simultaneous connection of the patient to the Striat and to surgical equipment of high frequency can cause burns in the application area of the electrodes and it may damage the stimulator. The operation at a short distance (1 meter for example) from shortwave or microwave therapy equipment can produce instability in the output of the equipment. In order to prevent electromagnetic interference, we suggest that one group of power supply line is used for Striat and another separate group for the short wave and microwave equipment. We also suggest that the patient, Striat and the connection cables are placed at least at a distance of 3 meters away from the shortwave or microwave therapy equipment*

Radio frequency communication equipment, mobile or portable, may cause interference and affect the functioning of Striat.

Attention: The application of the electrodes close to the thorax may increase the risk of cardiac fibrillation.

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STRIAT Description

Striat uses microcomputer technology, that means, it is **microcontrolled**. It was designed following the existing technical manufacturing standards for medical equipment (NBR IEC 60601-1 NBR IEC 60601-1-2 and NBR IEC 60601-2-10).

Essential Performance – STRIAT is an electrostimulator unit of simple operation, therefore becoming essential in the area of esthetics (dermal-functional) and trauma-orthopedics. It is a direct current equipment (galvanic in milliamperes) and *direct microcurrent* (galvanic in microamperes), *with the aim of accomplish ionization and render support in the treatment of wrinkles and stretch marks.*

The technique consists of the application of a soft electrical stimulation through electrodes placed on body areas. This technique is noninvasive, without systemic effects, it does not cause dependency and it does not have undesirable side effects. The current intensity necessary for the treatment depends on the sensation of the patient. Thus, the treatment must start with minimum intensity levels (very low), carefully increased until obtaining the adequate effects of the procedure and according to the reaction of the patient. When a person is subject to different types of current, they will feel a pricking sensation on the place or areas between the electrodes. That sensation is usually comfortable for most people. The degree of sensation is controlled by the adjustment of the parameters (controls) of the equipment. Due to the fact that the utilized technology is the same microcomputer technology, these controls operate using the touch screen. All the information regarding the parameters chosen by the professional therapist will be shown in the numeric display.

It is a device with modern characteristics and with advanced technology, that makes it effective and safe.

STRIAT – AC INPUT

STRIAT is a CLASS II monophasic equipment with BF applied part of safety and protection. Striat is a bi-volt equipment, that is, the commutation 110/220 volts is automatic. It is not necessary to be concerned regarding the voltage of the local power supply line. Just plug in the equipment to the “power outlet” and the equipment will perform, automatically, the selection to 110/220 volts.

The connection cable to the electric line is detachable.

The equipment uses the line plug as a resource to separate electrically the circuits of the power line in all the poles.

ATTENTION:



On the rear part of the Striat, is located the protection fuses. To replace them, turn the equipment off, unplug it from the power outlet and, with a small screwdriver, take the protective lid off, disconnect the fuse, perform the replacement and put the lid back to its original place.

Always use fuses recommended by IBRAMED:

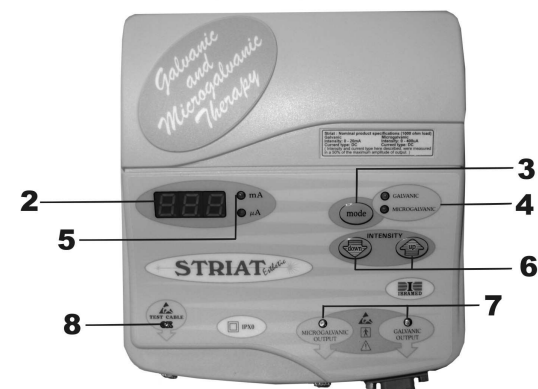
Use fuse of 2 A (20 AG)

SECURITY RISKS MIGHT OCCUR IF THE EQUIPMENT IS NOT PROPERLY INSTALLED.

OBS: There are dangerous voltages inside them. *Never open the equipment.*

STRIAT – Controls, indicators, and operation

VISTA DO PAINEL



VISTA DO FRONTAL



VISTA DA TRASEIRA



1- **On-OFF** key.

2- **Display that indicates the intended intensity of microgalvanic current (uA) or galvanic current (mA) one.**

3- MODE key – this key allows select microgalvanic or galvanic current. Once selected microgalvanic current, the intensity can be chosen from 10 to 400 uA (steps of 10 uA). Once selected galvanic current, the intensity can be chosen from 0 to 20 mA (steps of 1 mA).

4- Light indicators of the selected current: Galvanic ou Microgalvanic.

5- Light indicators of selected current unit:

mA – milliamperes

uA – microamperes

6- UP/DOWN keys: 2- **Selected keys that indicates the intended intensity of microgalvanic current (uA) or galvanic current (mA) one.**

UP key – increase the speed

DOWN key – decrease the speed

7- luminous (yellow) indicators of the presence of an output current intensity for the patient that may present a resistance to a charge of 1000 ohms, a tension higher than 10 V or a current higher than 10 mA.

8- Light indicator OK – it indicates the integrity of electrode cables type pen with needle.

9- GALVANIC OUTPUT: connection of cable of galvanic current for the patient.

10- MICROGALVANIC OUTPUT: connection of cable pen electrode cable with needle of microgalvanic current for the patient.

11- TEST CABLE: connection for electrode test type pen with needle. Connect this electrode on TEST CABLE and plug the contact with the end of pen electrode. Indicator OK will light up indicating that the cable is not damage.

OBS: This electrode is used on applications with microgalvanic current in the treatment of wrinkles and stretch marks.

12- Power cable port to be connected to the power supply line.

13- Fuse Rack (read in this manual – AC input)

Direct current or GALVANIC

Galvanic current, also called continuous current, is defined as a current in which the movement of the charges of the same signal goes in the same direction with a fixed intensity. The term continuous indicates that the intensity of the current is constant in value and direction.

The application of galvanic current can be divided into: galvanization per se and iontophoresis (ionization).

GALVANIZATION

Galvanization is the use of galvanic current, exclusively using polar effects (which are only produced under the electrodes) caused by it.

Biological tissues present a large amount of positive and negative ions dissolved in body liquids, which can be put into ordered motion using a polarized electrical field, applied on the surface of the skin. This movement of the ions inside the tissues have important consequences, firstly physical and consequently chemical, they can be grouped into the following categories:

- Electrochemical effects
- Osmotic effects
- Vasomotor modifications
- Excitability alterations

Besides these ionic transference polar effects, there will be other effects denominated inter-polar effects during galvanization:

- Electrophoresis
- Electroosmosis
- Vasodilation of the skin
- Electrotonus

Electrophoresis – According to DUMOULIN (1980), is the migration under the influence of continuous current of colloidal solutions, blood cells, bacteria and other simple cells, this phenomenon is caused by the absorption or opposition of ions.

Electroosmosis – Under the influence of the electrical charge acquired by the membrane structures, a modification of the water contained in the tissues is produced.

Vasodilation of the skin – All chemical reactions and alterations of connections that occur in the presence of continuous current, release energy and alters the local temperature.

Electrotonus – It can be called electrotonus or electronic potential, these are local electrical modifications produced by electrical current in the resting potential of the cellular membranes.

At the start of the application, the patient will report a slight pricking sensation. The sensation becomes a more intense pricking, burning and pain with the gradual increase of the intensity.

Galvanic current transfers ions from one pole to the other by passing through the tissue. There is an electrolytic dissociation of tissular sodium chloride (NaCl) in sodium cations (Na) and chloride anions (Cl). The chloride anion will migrate into the positive pole of the electrode, as carrier of the negative charge and losing its negative charge and thus reacting and turning into molecular chloride (Cl₂). The same occurs with sodium, which when migrating into the negative pole will lose its electron, reacting and transforming into metal sodium (Na).

Hyperthermia becomes active due to the action of galvanic current on the vasomotor nerves, producing through the negative pole in a more significant manner. The vasomotor nerves remain hypersensitive for a considerable amount of time. Hyperemia also reaches deeper structures through a reflex action. Thus, there is an increase of blood irrigation, carrying deeper tissudal nutrition (subcutaneous, fascias and superficial muscles). Hyperemia causes higher oxygenation, increase of metabolism, increase of metabolized substances.

The presence of metabolites produces vasodilation of arterioles and capillaries as a reflex which leads to an increase of the blood flow, higher amount of nutritious substances, more leukocytes and antibodies, increasing the repair capacity of the area.

IONTOPHORESE

Iontophoresis or ionization, also denominated ionic transfer, is the penetration of substances into the body, through galvanic current, which is the best method for the ionic transport of the applied substance through its constant and unidirectional emission of an electrical flow.

Iontophoresis has been used for more than a century; it is even mentioned in literature from the 17th and 18th centuries. The substances used in most cases are basic elements associated to different radicals of physiological value.

When two metal electrodes which are connected to a continuous current source are applied on a body area in contact with an electrolytic solution, there is a possibility to promote the transfer of ions into the tissue, the polar properties of galvanic currents are used in this way.

The passage of galvanic current through an electrolytic solution produces ions, electrically charged particles, dissolved or suspended in the solution, migrating in accordance with the electrical charge.

The basis of the success of the ionic transfer lies on the basic physical principle “similar poles repel and opposed poles attract”, the selection of the ionic polarity is correct and its performance with the similar polarity of the electrode for administration is of more importance.

Iontophoresis associates the polar effects of galvanic current to the inherent effects of the used drug, therefore it is very effective for several protocols of esthetic area..

GUIDELINES FOR APPLICATION OF GALVANIC CURRENT

- Experiments have demonstrated that low intensities are more effective as a directional force, than high intensities of the current;
- The intensity of the current must not exceed 0.1 mA/cm² of the active electrode area;
- Usually, the negative electrode must be larger, due to the fact that it is more irritating than the positive electrode.
- There is a need for correct coupling between the electrodes and the skin and correct humidification of the pads to reduce resistance and avoid burns;
- Metal electrodes must be used, preferentially aluminum, for polarized currents;
- Solutions of continuity (wounds, ulcers, etc.) may concentrate ionic flow and cause burning;
- After ionization, the pads must be washed in order to remove the used chemical residuals;
- There is no advantage in using a solution with a higher concentration than what is indicated by the manufacturer.

INTRAORAL GALVANISM

It has been proven that low galvanic currents associated with electrogalvanism are continuously present in the buccal cavity. Galvanic currents may cause unfavorable consequences, not only on metal fillings, but also on teeth and bulky tissue.

When two metal materials with different potentials are in contact in the presence of an electrolyte, a difference of potential occurs, this is a transference of electrodes. Thus, galvanic corrosion occurs, which results from the coupling of different metal materials immersed in an electrolyte, causing transference of electrical charge from one another, due to the fact of their different electrical potentials. It is characterized by presenting localized corrosion, close to the coupling region, causing deep perforations on the metal material that works as an anode. Unfortunately, the oral environment is very conductive.

SOMETHING ABOUT STRETCH MARKS

In the available literature on stretch marks, authors are unanimous to consider them an irreversible sequela.

Study from Guirro and col. (1990), using filtered and constant direct current of some microamperes (microgalvanic), have opened a new perspective on the stretch treatment. Preliminary data showed that a significative increase of the number of young fibroblasts occurs, as well as a neovascularization and the return of painful sensation after some electrostimulation sessions. The efficiency of treatment, once controlled the variables, can reach 100%, depending on the capacity of reaction of each patient, altering the number of sessions according to the color of skin, the age and the size of the stretch marks. It is important the absence of promise of total elimination of the stretch Mark, once it is impossible foresee the result for all individuals.

It is important that the treatment starts in a homolateral way, offering a side of control for macroscopic observation of the evolution of treatment. When the repair is perceptive, start the treatment in the contralateral side.

The invasive method and the process of stretch mark regeneration is based on the intrinsic effects compilation of direct current and of processes related with acute inflammation. Because it is an invasive technique, there is necessity of question the patient about his/her predisposition for the arising of cheloids, utilization of medicines, integrity of skin, etc. (assessment sheet).

TECHNICAL PROCEDURE

To accomplish the antistrech marks treatment, it is necessary a special active electrode, which consists of a thin needle supported by an electrode type pen. The passive electrode is type plate. Due the electrodes have different sizes, the small one, the needle, presents higher concentration of current. The ideal band for treatment of stretch marks is concentrated in the band from 70 up to 100 microamperes (uA), and it can be alternated depending on the sensitivity of the patient.

STRIAT has an intensity enough for the wrinkle treatment, in which the current intensity changes from 150 up to 400 uA. The intensity can not be highly increased for the treatment of stretch marks because it is an invasive treatment.

The technical procedure consists in the coupling of passive electrode, previously dampy in water, to the patient. The active electrode, the needle, should be sterilized each treatment beginning. We suggest the use of detachable needles. Because it is an invasive treatment, the stimulated area should be sterilized each session.

The introduction of needle should be subepidermic, parallelly to the skin, and superficially on the whole extension of the stretch mark. It is necessary to get a hyperaemia and edema frame on all the stretch mark extension. In the ending of the treatment, we observe more visible, swollen and hyperemic stretch marks. It should not effectuate a new application until this condition has been completely disappeared.

In deep stretch marks, the sensitivity is altered and, thus, in the beginning of treatment (days or weeks) the patient could not report pain. As the applications go by, a condition of pain perfectly bearable can arise with the same intensity of an application in normal skin. Due to the bilaterality condition of stretch marks, they should be unilaterally stimulated in the beginning of treatment, leaving the contralateral for control with the purpose of compare them.

In the final phasis of treatment, when the appearance of the skin is already according to the normal standards, a rupture of small vases can occur because of neovascularization. Petechias will be completely absorbed from one to three days.

The first signs of regenerations of stretch marks are: 1- the leveling of the stretch mark related to the normal skin (they can even become larger); 2- alteration of color; 3- increase of painful sensitivity and, at least 4- the stretch mark disappearance.

Each patient should have an individual needle, if possible a detachable one, or it can be immersed in a no oxydant and sterilitant liquid in order to avoid contamination,

The sequence and the number of applications vary according to the individual response of each patient.

In the treatment of wrinkles and expression lines, the intensity will be given according to the patient sensitivity, that means, if his/her skin is a dry one, he/she can feel less sensations; if the skin is an hydrated one, it is the contrary.

The procedure in wrinkles can be either an invasive one or not, and the interval between the sessions depends on the way of application. If the procedure is an invasive one, the interval should be at least of 3 days between the sessions.

FACTORS RELATED TO THE TREATMENT BY DIRECT MICROCURRENT

- All factors that modify the quality of the inflammatory response, will affect the treatment.
- If the patient presents high levels of glicocorticoides, endogenous or exogenous, like the Cushing Syndrome, the application can not be done because of low results and risk to the patient.

If the stretch marks occur durant the pregnancy, the treatment can only be start after the hormonal levels became to the same levels before the pregnancy.

- The treatment can not be start on puberty because of high volume of hormonal changes, described by some specialists as a cause of appearance of stretch marks.

Use instructions – Learning how to use STRIAT

Procedure to turn on the device:

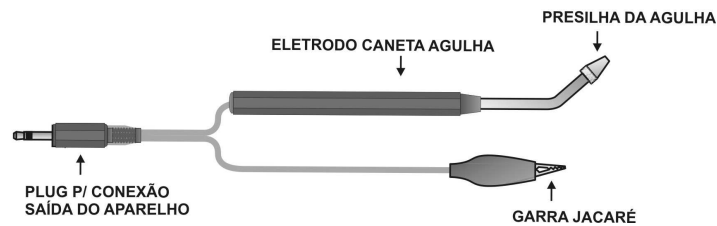
- Connect the power cable to the equipment and the power plug in the power supply line of either 110 volts or 220 volts. The equipment is a bivolt one, thus, the selection 110/220 volts is automatic.
- Press the key (1); the indicator display of intensity (2) will light up.
- By means of the MODE (3) key, select the type of current necessary to the treatment: microgalvanic current (wrinkles and stretch marks) or galvanic current (ionization).
- If the chosen current is the galvanic one, turn the application cable on in the galvanic output (9).
- If the chosen current is the microgalvanic one, first of all turn the electrode – pen – needle application cable on in the TEST CABLE (11), and test the cable. Put the application cable terminals in contact (tip of the pen and clip in short). The light indicator OK (8) should light on indicating the cable is complete. Disconnect it from the test cable and connect it to the MicroGalvanic OutPut (10).
- Put the needle in the electrode type pen. With the patient completely prepared, increase the intensity of the current necessary for the treatment by means of the intensity control (6).

Use Instruction -

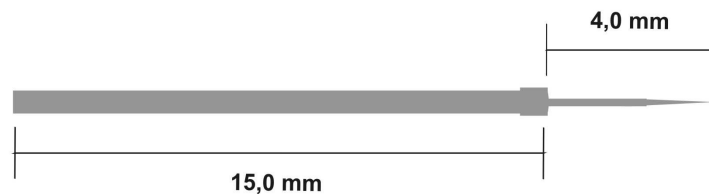
How to put the needle in the electrode type pen

Step 1:

Vista geral do eletrodo caneta agulha:

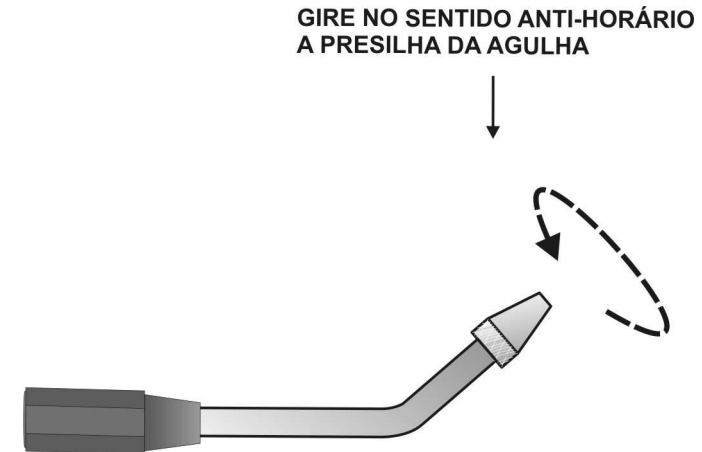


Vista geral da agulha:

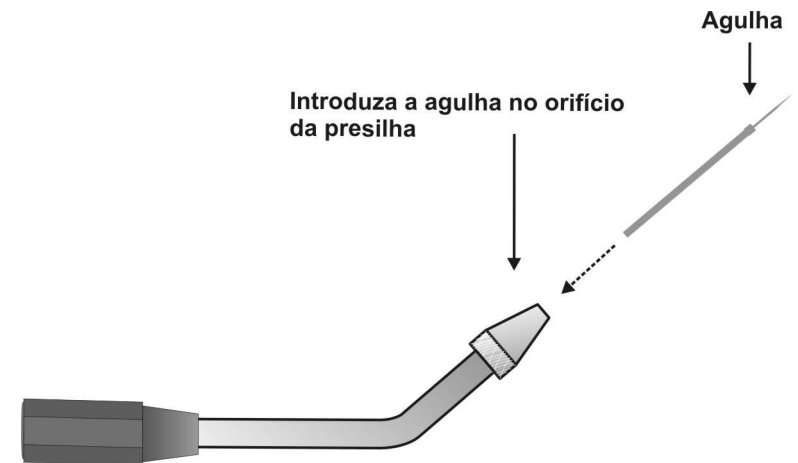


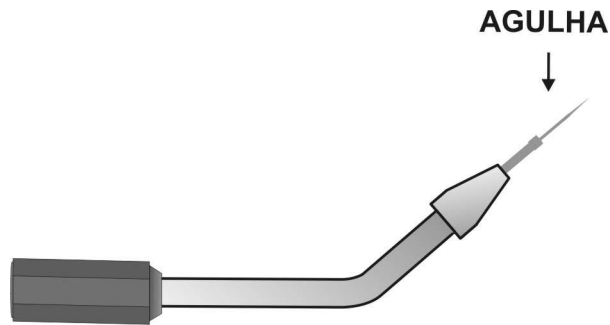
Note: approximate size of the needle in millimeters

Step 2: Introduction of the needle in the pen electrode – the needle should be inserted and hold in the extremity of the pen electrode. For this, free the needle clip turning it in clockwise.



Step 3: Insert around 10 mm the needle into the clip opening.





Step 4: Turn the needle clip clockwise in order to the needle is hold.



Use Instruction -

General care with the needle

BIOSECURITY – It can be defined as: “policies and measures taken to protect from biological harm. It encompasses the prevention and mitigation from diseases, pests, risks that can produce damages to the human health, animals, environment or quality of the services”.

The major causes of accidents are related to:

- Unsuitable instruction
- Inefficient supervision
- Improper use of Individual Protection Equipments (EPI)
- No following of existent rules.
- Improper practices.
- Defective planning.
- Excessive day's work.

For good practices of service to patients, it is necessary to know some rules and the safety procedures in order to minimize the risks of accidents.

It is necessary to point out some cares during the use of needles in the treatment of wrinkles and stretch marks.

- When you introduce a needle, never touch its blade. We suggest the use of gloves.
- When removing the needles, pay attention to avoid accidents. The needles should be rejected in a proper recipient according to guidelines described in the next page.
- In case of use of no detachable ones, use antiseptic chemical products.

OBS: We recommend the use of one-time use needles.

Rejection of the needle:

GROUP – BLUNT FORCE PUNCTURE – they are the objects and tools that have corners, borders, points or rigid and sharp protuberances, able to cut and perforate a body.

They can be joined in this group: blades to shave, scalpels, **needles**, dissecting knives, flasks in glass, blades and other similar objects derived from health centers.

Needles should be thrown away separately in the place of their generation immediately after its use. They should be kept into rigid covered recipients resistant to puncture, rupture, and leakages.

Antiseptic chemical product:

In case of use of no detachable needles, we suggest the use of Glutaraldehyde.

Action mechanism – it changes ADN, ARN, and protein synthesis.

Action scope – bactericide, fungicide, microbactericide, and sporicide.

Concentration - 2%

Exposure time – from 45 to 60 minutes.

Indication – for high level disinfection.

It demonstrates germicide activity before organic material, however the needle in glutaraldehyde, with no previous cleaning, can present blood and secretions impregnated by the formation of precipitates, and that makes difficult the cleaning in a special way. The product should be handled in a ventilated place with use of EPI.

Observation: Materials with excessive porosity like latex ones can retain the glutaraldehyde, if there isn't a good rinsing.

Reminders:

CARES TO BE OBSERVED DURING THE INSERTION OF NEEDLES

- Keep the material to be used in a sterile place;
- The needle extremity should be kept sterile before its penetration;
- After the cleaning (sterilization) of the patients' skin, do not touch the insertion point.
- The one-time use needles (sterilized) should be kept in their original packing and kept in a proper place where there is no risk of contamination.

CAUTION AND COUNTER-INDICATIONS

Patients bearers of:

- Diabetes
- Hemophilia
- Cushing Syndrome
- Propension for cheloids
- Psoriasis
- Vitiligo
- Anti-inflammatory without corticoide (only for prompt application)

Patients that use:

- Steroid
- Corticosteroids

Bibliographic References

Guirro, E.C. ; Ferreira, L. and Guirro, R.R.J. Preliminary Studies on the Effects of Low Intensity Galvanic Current in Treatment of Atrophic Stretch Marks of Human Cutis. Anais do X Congresso Brasileiro de Fisioterapia (Fortaleza, CE, 1991).

Guirro, E.C. ; Ferreira, L. and Guirro, R.R.J. Estria. In.; Fisioterapia em Estética – Fundamentos, Recursos e Patologias. São Paulo, Editora Manole, 1992.

Guirro; E.C.O e Guirro; R.R.J. : Estria In.; Fisioterapia em Estética – Fundamentos, Recursos e Patologias. São Paulo, Editora Manole, 1996.

ELECTRODES – RECOMMENDATIONS – STRIAT allows transcutaneous neuromuscular stimulation with galvanic current and microgalvanic current. For that we employ electrodes of vegetal sponge - aluminum 80 x 100 mm and/ or pen electrode with needle in the extremity, these ones supplied with the equipment. The size (area in cm^2) of the electrodes used in electrostimulation is very important;

- We recommend you using only electrodes supplied as STRIAT accessories in size 80 x 100 mm. The application method of these electrodes is very simple. The 80 x 100 mm aluminium electrodes used should be put into the vegetable sponge “little packet” and the fork-clip of the connection cable to the patient should be put in the aluminium electrode.
- If the user wants to employ another type of electrode, we recommend always the ones in size bigger than those that are supplied as accessories.
- Electrodes in smaller sizes than those that are supplied as accessories can cause skin burnings and irritations. If is necessary employ smaller electrodes, we recommend that the current density does not surpass 0.1 mA/cm^2 . If there is necessity of surpass such values, the user should observe some possible damaging effects (NBR IEC 60601-2-10).
- The maximum values of output current for the patient supplied by this equipment do not surpass the density limit of current specified by the rule NBR IEC 60601-2-10. Thus, with the recommended electrodes the equipment can be operated with maximum output, if necessary.
- Some chemical products (gel, lotion, etc) can damage electrodes, decreasing their lifetime.
- After using the electrodes, clean them with running water. Always clean the electrodes before keep them.

Attention: The application of the electrodes close to the thorax may increase the risk of cardiac fibrillation.

ELECTRODES – BIOCOMPATIBILITY (ISO 10993-1): IBRAMED declares that aluminum, vegetal sponge electrodes, and pen with needle electrodes supplied with the equipment do not cause allergic reactions. These electrodes should be only put in contact with the intact surface of the skin by respecting a limit of time of 24 hours for such a contact. There are no risks of harmful effects to the cells, nor is there any allergic reaction or of sensitivity. The electrodes in silicone rubber do not cause potential irritation in the skin.

Durability of the electrodes – Wear of the aluminum-vegetable sponge electrodes and needles from the electrode pen is normal with time and use. A worn electrode will lose uniformity in the conduction of electrical current, giving a sensation that the equipment is weak. Electrical conduction points may also appear, where the current density will be very high which may cause an uncomfortable sensation to the patient. Change the electrodes at least every six months, even if they **have not been used or even monthly in case of intense use.**

Environmental Protection: IBRAMED declares that there are no risks or special techniques associated with the elimination of this equipment and accessories at the end of their useful lives.

ELECTRODES CLEASING

After using the electrodes, clean them with running water. Always clean the electrodes before keep them.

MAINTENANCE

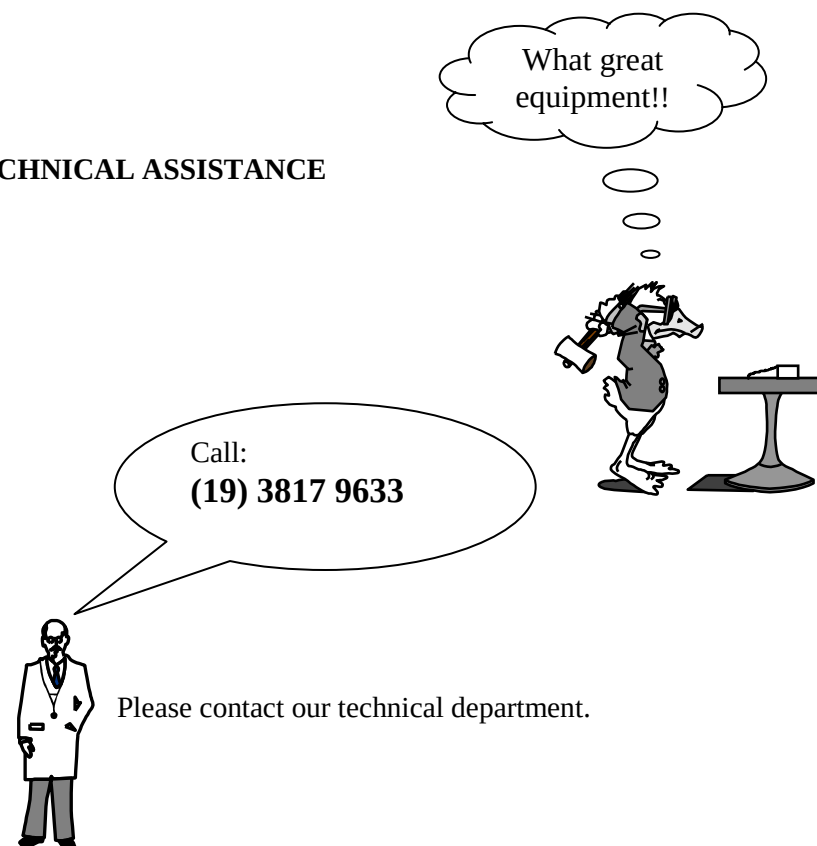
We suggest that the user inspects the equipment and performs preventive maintenance at IBRAMED or at the sales point **each 12 months** the equipment is used. As manufacturers, IBRAMED is deemed responsible for technical or safety characteristics of the product **only in cases** when the unit has been used in accordance with the instructions contained in the user's manual, and where maintenance, repairs or modifications have been made by the manufacturer or by expressly authorized agents, and where the components which can cause safety risks and also where components for the proper functioning of the equipment have been substituted, in case of repairs, with original substitution parts.

If required, IBRAMED will be able to make available the technical information necessary for eventual repairs of the equipment (circuit schemes, list of parts and components, etc.). However, this does not imply a repair authorization. We do not assume any responsibility for repairing performed without our express written authorization.

WARRANTY

IBRAMED, Indústria Brasileira de Equipamentos Médicos LTDA, herein identified to the consumer at the address and telephone number: Rua Milão, 50 – Amparo – SP, telephone number +55 (19) 38179633, guarantees this product for the period of eighteen (18) months, observed the conditions of the warranty terms attached to the documentation of this equipment.

TECHNICAL ASSISTANCE



And now?



TROUBLESHOOTING

What might seem to be a problem at first sight, may not always be a malfunctioning. Therefore, before contacting the technical assistance, check the items described on the table bellow.

Problems	Solution
The equipment does not turn on 1	Is the power cable properly connected? If it is not, connect it. Also check the power outlet on the wall.
The equipment does not turn on 2	Have you checked the protection fuse? Check if they are properly connected. Check also if the value is in accordance with the indicated in the operation's manual.
The equipment is on but does not emit current to the patient 1.	Have you followed the recommendations and instructions in the operation manual correctly? Check and go through the steps described in the chapter about <i>controls, indicators e operation</i>.
The equipment is on but does not emit current to the patient 2.	Have you checked the electrodes and the connection cables? Check if the cable plug is properly connected to the equipment. Check if the electrodes are correctly placed to the patient body.

Warranty Term

1) Your IBRAMED product is certified against manufacture defects, if considered the established conditions in this manual for 18 following months.

2) The period of warranty will count from the first purchase date by the consumer, even when the product is transferred to a third party. The replacement of parts and the cost in repairs of malfunctions originated from manufacturing will be comprehended in the warranty.

3) The warranty procedures will be exclusively made by IBRAMED sales points, by IBRAMED itself or by other parties specifically designated by IBRAMED.

4) WARRANTY DOES NOT COMPREHEND DAMAGES WHICH COULD OCCUR TO THE EQUIPMENT IN CASE:

The equipment is not used exclusively for medical purposes.

The specifications and recommendations in the user's manual are not observed in the installation and use of the equipment.

Accidents or natural hazards, connection to electrical system with inappropriate voltage, and/or excessive fluctuation or overcharge/ over voltage occur.

The equipment is not handled properly, is not taken proper care of, or suffers alterations or repairs made by not certified people or companies.

There is removal or adulteration of serial number of the equipment.

Any accident in transportation occurs.

5) Legal warranty does not cover: expenses with installation of product, installation of software, installation of microcomputer, transport of product to the factory or sales point, labor cost, materials, parts and adaptations necessary to the preparation of the premises where the equipment will be used, such as: electric wiring, computer technician expertise, masonry, hydraulic installations, grounding system, as well as its adaptations. The warranty does not cover either parts subjected to wear and tear such as: command switches, control keys, handles and mobile parts, sucker applicators, application pens for microderm abrasion, power cable, connection cables to the patient, transducer cables, conductive silicon rubber applicators, diathermy applicators, batteries, ultra-sonic transducer (when improper use or its fall is proved), equipment cabinet.

6) No sales point of IBRAMED has authorization to alter the conditions here mentioned, or to take any commitment in the name of IBRAMED.

Aparelho :
Número de série :
Registro Anvisa (MS) :

Data de fabricação :

Prazo de validade : 5 anos

Engenheiro responsável : Maicon Stringhetta

CREA - 5062850975

STRIAT – Accessories

02 80 x 100 mm aluminum-vegetable sponge electrodes
 01 pen with needle electrode cable with connection to the patient (for microgalvanic one)
 01 cable with red and black clips for ionization of connection to the patient (galvanic current)
 01 elastic belt with velcro
 01 detachable power cable
 Packing with 10 sterilized needles
 01 manual of instructions

The use of cables, electrodes and other accessories different from those specified above, may result in the increase of emissions and in the decrease of the equipment immunity.

STRIAT – Technical Characteristics

Striat is a equipment designed for *continuous operation mode*. It uses microcontrollers which guarantees the precision of the values displayed. This exactitude of the operation data is in accordance with what is prescribed by the particular standard for the safety of neuromuscular stimulation equipment – NBR IEC 60601-2-10, clause 50 / sub-clauses 50.1 and 50.2. The control of the output amplitude continuously controls the intensity of the current from the minimum to the maximum and its minimum value exceeds 2% of the value at the maximum position. Parameters such as output wave shapes, pulse duration, pulse repetition frequency, output current amplitude range do not differ more than $\pm 30\%$, mentioned in the following technical description.

The values of the Duration of the pulses and pulse repetition Frequencies described here were measured at 50% of the maximum output amplitude.

These parameters are valid for a charge impedance of 1000 ohms. The charge impedance effect in the described parameters is very important. If the device is operated out of the band of the specified charge impedance, it could be inexactness in the values

of parameters, as well as alteration of wave forms here described.

STRIAT is a CLASS II monophasic equipment with BF applied part of safety and protection.

AC input.....110 / 220v (60 Hz) automatic
 Maximum amplitude of microgalvanic current-----400 μ A
 Maximum amplitude of galvanic current-----20 mA
 Type of pulse-----constant filtered direct current
 Input power - Consume (max.):.....35 VA
 Weight (approx. without accessories):-----460 g
 Maximum stacking number:.....10 boxes
 Temperature for transport:.....5 to 50⁰ C
 Room Temperature for work:.....5 to 45⁰ C

Note: The equipment and its characteristics are subject to change without previous notice.

Electromagnetic Compatibility:

STRIAT was designed to comply with the requirements determined by norm IEC 60601-1-2 of electromagnetic compatibility.

The objective of this norm is:

- to guarantee that the level of the spurious signals generated by the equipment and irradiated to the environment are below the limits specified in the norm IEC CISPR 11, group 1, class A (radiated emission).
- to guarantee the immunity of the equipment to electrostatic discharges, by either contact or air, stemming from the accumulation of electrical static discharges acquired by the body (Electrostatic Discharge – IEC 61000-4-2).
- to guarantee the immunity of the equipment when submitted to an electromagnetic field inciding from external (Immunity to Irradiated RF - IEC 61000-4-3).

Precautions:

- *The operation at a short distance (1 meter, for example) of a short wave or microwave equipment can produce instability in the output of the equipment .*
- *In order to prevent electromagnetic interference, we suggest that one group of power supply line is used for STRIAT and another separate group for the short wave and microwave equipment. We also suggest that the patient, STRIAT and the connection cables are placed at least at a distance of 3 meters away from the shortwave or microwave therapy equipment.*
- *Radio frequency communication equipment, mobile or portable, may cause interference and affect the functioning of STRIAT. Always install this equipment according to the guidelines described in this manual of instructions.*

Attention:

- STRIAT complies with all the technical norms of electromagnetic compatibility if the cables, electrodes and other accessories supplied by IBRAMED and described in this manual are used. (chapter: Accessories and technical characteristics).
- *The use of cables, electrodes and other accessories from other manufacturers and/or different from those specified in this manual are used, as well as the substitution of internal components of STRIAT, this can result in increase of emissions or decrease in the equipment immunity*
- *STRIAT must not be used adjacently or stacked on top of other pieces of equipment.*

Directions and Manufacturer's Statement – electromagnetic emissions		
Thermopulse Automatic Tuning is designed for use in electromagnetic environments specified below. The user of the equipment must ensure that it is used in such an environment.		
Emission Assay	Conformity	Electromagnetic Environment - directions
RF Emissions NBR IEC CISPR 11 IEC CISPR 11	Group 1	STRIAT electrostimulator uses RF Power supply only for its internal functions. However, its RF emissions are very low and unlikely to cause any interference in nearby electronic equipment
RF Emissions NBR IEC CISPR 11 IEC CISPR 11	Class A	STRIAT electro-stimulator is adequate for use in all premises which are not residential and not directly connected to the public low tension electric power distribution line which supplies buildings appropriate for domestic use
Harmonics Emission IEC 61000-3-2	Class A	
Emissões devido à flutuação de tensão/cintilação IEC 61000-3-3	Classe A	

Directions and Manufacturer's Statement - electromagnetic immunity			
STRIAT electro-stimulator is designed for use in electromagnetic environments specified below. The user of the equipment must ensure that it is used in such an environment.			
Immunity Assay	Level of Assay IEC 60601	Level of Conformity	Electromagnetic Environment - directions
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV per contact ± 8 kV by air	± 6 kV per contact ± 8 kV by air	The flooring must be either wooden, concrete or ceramic. If the flooring is covered with synthetic material, the humidity must be of least 30%.
Rapid electric transitory / train pulse (Burst) IEC 61000-4-4	± 2 kV in the Power lines ± 1 kV in the input /output lines	± 2 kV in the Power lines ± 1 kV in the input /output lines	The quality of the power supply should be equivalent to the one of a hospital or a typically commercial establishment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV regular mode	± 1 kV differential mode ± 2 kV regular mode	The quality of the power supply should be equivalent to the one of a hospital or a typically commercial establishment.

Immunity Assay	Level of Assay IEC 60601	Level of Conformity	Electromagnetic Environment - directions
Tension falls, short interruptions and tension variations in the input power lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ of tension fall in U_T) per 0.5 cycle $40\% U_T$ (60% of tension fall in U_T) per 5 cycles $70\% U_T$ (30% of tension fall in U_T) per 25 cycles $< 5\% U_T$ ($> 95\%$ of tension fall in U_T) per 5 seconds	$< 5\% U_T$ ($> 95\%$ of tension fall in U_T) per 0.5 cycle $40\% U_T$ (60% of tension fall in U_T) per 5 cycles $70\% U_T$ (30% of tension fall in U_T) per 25 cycles $< 5\% U_T$ ($> 95\%$ of tension fall in U_T) per 5 seconds	The quality of the power supply should be equivalent to the one of a hospital or a typically commercial establishment. If the user of the equipment requires continuous operation during energy interruption, it is recommended that the equipment should be fed by a source of uninterrupted power supply or a battery.
Magnetic Field in the frequency of Power feed (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in the frequency of power supply must be on the same levels characteristic of a hospital environment or a typically commercial establishment.
NOTE: U_T is the c.a. power feed tension before the application of the assay level.			

Directions and Manufacturer's Statement - electromagnetic immunity

O eletro-estimulador STRIAT é destinado para uso em ambiente eletromagnético especificado abaixo. O usuário do equipamento deve assegurar que ele seja utilizado em tal ambiente.

Immunity Assay	Level of Assay IEC 60601	Level of Conformity	Electromagnetic Environment - directions
RF Conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	RF Communication equipment, portable or mobile, must not be used next to any part of STRIAT, including cables, with a separation distance of less than the recommended, calculated from the equation applicable to the frequency of the transmitter. Separation distance recommended $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz up to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz up to 2.5 GHz
RF Radiated IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Where P is the maximum output nominal potency of the transmitter in watts (W) according to the manufacturer of the equipment, and d is the separation distance recommended in meters (m). It is also recommended that the Field intensity established by the RF transmitter, as determined by an electromagnetic inspection at the site should be lower than the conformity in each frequency band ^a . Interference around the equipment marked with the following symbol might occur: 

NOTE 1: In 80 MHz and 800 MHz highest frequency band is applied.

NOTE 2: These directions may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

^a The Field intensities established by the fixed transmitters, such as base radio stations, telephone (cellular/wireless) and mobile terrestrial radios, radio amateur, transmission radio AM and FM and TV transmission cannot be theoretically predicted with accuracy. To evaluate the electromagnetic environment due to fixed RF, an electromagnetic, it is recommended to check the local. If the field intensity measurement at the local where STRIAT is used, exceeds the level of conformity used above, the equipment must be observed in order to verify whether the operation is normal. IF an abnormal performance is observed, additional procedures may be necessary, such as reorientation or the reinstalling of the equipment.

^b Above 150 KHz to 80 MHz frequency band, the field intensity should be lower than 10 V/m.

Recommended Separation Distances between portable and mobile RF and STRIAT			
The STRIAT electro-stimulator is conceived to be used in electromagnetic environments in which RF disturbances are controlled. The user may help to prevent electromagnetic interferences by keeping a minimum distance between the portable and mobile RF communication equipment (transmitters) and STRIAT, as recommended below, according to the maximum potency of the communication equipment.			
Maximum Nominal Output potency of the transmitter W	Distance of Separation in accordance with the frequency of the transmitter m		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7
For transmitters with a maximum nominal output potency not listed above, the separation distance recommended in meters (m) may be determined by an equation applicable to the frequency of the transmitter, where P is the maximum nominal output potency in watts (W) according to the manufacturer of the transmitter. NOTE 1: From 80 MHz to 800 MHz, the distance of separation relative to the highest frequency band is applied. NOTE 2: These directions may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.			

FREE TECHNICAL ASSISTANCE CONTRACT

DETACH AND SEND THIS PAGE TO IBRAMED

In order to better serve you in future, please answer the following questions:

1- Your choice of this IBRAMED product was based on:

- ☐ newspaper or specialized magazines
☐ sales representative advice
☐ friend's advice
☐ exhibitor or showroom
☐ manufacturer's image
☐ technical assistance

2- Have you already owned similar equipment before?

- ☐ yes, IBRAMED ☐ yes, other brands ☐ no

3- In your opinion, what is considered as being more important in an equipment:

- ☐ aspect / appearance
☐ resources – versatility, assistance, technology, etc.
☐ price

4- How old are you?

- ☐ under 25 years old ☐ from 25 to 40 years old ☐ over 40 years old

5- Compared to your monthly wages, would you say the price of the equipment is:

- ☐ inexpensive ☐ reasonable ☐ expensive ☐ exaggerating

6- Which was the payment modality?

- ☐ cash ☐ installment

7- Please, make any comments here, either positive or negative, which you find relevant:

.....

Name :-----

-----**DOB** ---/---/---

Address:-----

District :----- **City:**-----

-----**State:**-----

ZIP Code:-----**Tel.:**-----

Equipment:----- **Serial Number:**-----